

# **Food and Drug Administration**

**Center for Drug Evaluation and Research**

## **Advisory Committee for Pharmaceutical Science**

**DAY 1: May 3, 2005**

### **Questions**

1. Are the tactical steps outlined consistent with the QbD goals we seek to achieve?
2. What additional steps and/or changes would you recommend to improve this plan?
3. What additional scientific evidence is necessary to support the development and implementation of this plan?
4. General considerations for identifying and developing statistical procedures
5. Any other specific recommendations?
6. Prioritization?